

### **REMARKS**

The Office Action mailed April 12, 2006 has been carefully considered and the following response prepared. Claims 58-76, 96, 98 100, 102, 103, 105, 106, 108, 109, 111, 112 and 114-139 are pending in the application.

Claims 58-76, 96, 98 100, 102, 103, 105, 106, 108, 109, 111, 112 and 114-139 have been canceled without prejudice and replaced with new claims 140-163 directed to methods for preparing a water-dispersible liquid vitamin food additive for animals and methods for dispersing a water-dispersible liquid vitamin food additive. Support for new claims 140-163 can be found in claims previously presented claims 58-60, 62, 65-66, 68-70, 100, 102, 105, 108, 111, 114-116, 118, 121-122, 124-126, 135 and 136-139, and throughout the specification, in particular at page 4, lines 6-8 and the Examples. No new matter has been added.

At page 2 of the Office Action, the Examiner rejected claims 58-76, 96, 98 100, 102, 103, 105, 106, 108, 109, 111, 112 and 114-139 as being unpatentable over Kirk (U.S. Patent 4,966,779) in view of each of Parfitt (Martindale 32<sup>nd</sup> edition, pp.1358-1359, 1366-1370), Winstrom et al. (U.S. Patent 3,708,583), Tipton et al. (U.S. Patent 5,747,058), Ames et al. (U.S. Patent 3,639,587) and Alderman et al. (U.S. Patent 4,678,516) and further in view of Bergemann et al. (U.S. Patent 6,096,699). The basis for the rejection is that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the vitamin compositions of Kirk or Winstrom et al. by incorporating alkyl lactate ester to the composition either as part of the solvent or a viscosity modulator because alkyl lactate esters are well-known pharmaceutical and food acceptable excipients and particularly as solvents or viscosity modulators, and further because alkyl lactate ester with fatty ester are known to form a safe solvent system.

Applicants traverse this rejection.

Claims 58-76, 96, 98 100, 102, 103, 105, 106, 108, 109, 111, 112 and 114-139 have been canceled without prejudice and replaced with new claims 140-163 directed to methods for preparing a water-dispersible liquid vitamin food additive for animals and methods for dispersing a water-dispersible liquid vitamin food additive.

Kirk discloses water-miscible emulsions comprising specific proportions of (a) 5-55% of a fat-soluble vitamin, (b) 3-30% of a liquid, edible vegetable oil, (c) 0.5 to 10% of a modified

lecithin, (d) about 10 to about 19% of a sucrose ester, (e) about 3.5 % to about 12% of sorbitan monooleate, (f) from about 16 to about 35% of a sugar alcohol and (g) from about 5 to about 30 % water. As shown in the Examples in Kirk the vitamin compositions are prepared by heating the vitamins and other ingredients prior to mixing. In Example 1 the vitamin component was heated to about 110°F and the other ingredients were heated to a temperature of approximately 120°F. In Example 2 the vitamin component was heated to 160°F and then cooled to approximately 120°F being added to the other ingredients which were heated to a temperature of approximately 120°F. The other examples were carried out in a manner similar to Examples 1 and 2. There is no disclosure or suggestion in Kirk of adding an alkyl lactate to the vitamin composition or of using precursors of the vitamins to prepare the vitamin compositions. Further, there is no disclosure or suggestion in Kirk of varying the temperature at which the process of preparing the vitamin compositions is carried out, and Applicants submit that a person of ordinary skill in the art would have understood that these temperatures are important to the process taught by Kirk and would therefore not have been motivated to alter the process.

Parfitt is directed to vitamin A compositions for administration to humans. Parfitt does not disclose a process for preparing an animal food additive.

Winstrom et al. discloses vitamin A additives for addition to animal feeds. Like Kirk, however, there is no disclosure or suggestion to add an alkyl lactate to the vitamin additive disclosed therein. Moreover, the formulations of the Winstrom et al. patent are alcohol based and are a different type of vitamin formulation than the formulations prepared by the claimed methods of the present application and the Kirk patent. One of the specific objects of the present invention was to avoid the use of the same types of alcohols that are used in Winstrom et al. because they are flammable. Thus, an artisan of ordinary skill would realize that the formulations of Winstrom et al. and Kirk are different classes of vitamin formulations and would not think that it was appropriate to combine the teachings of the two patents.

The compositions disclosed in each of Tipton, Alderman et al., Ames and Bergemann et al. are also very different types of compositions than the vitamin food additive made by the claimed methods. There is no disclosure or suggestion in any of the references that an alkyl lactate would be suitable for inclusion in a vitamin food additive for animals.

Tipton discloses compositions that form highly viscous depots when administered and are useful for the controlled release of substances. The compositions in Tipton comprise a non-polymeric, non-water soluble high-viscosity liquid carrier material of viscosity of at least 5,000 cP at 37°C that does not crystallize neat under ambient or physiological conditions and a substance to be delivered. Column 5, lines 50-57 of Tipton disclose mixing the high viscosity liquid carrier material with a viscosity lowering water soluble or water miscible solvent to form a lower viscosity liquid carrier material and then mixing the lower viscosity liquid carrier material with a substrate for controlled delivery. Column 10, lines 15-16 recite examples of suitable solvents, including ethyl lactate. The solvent is used to dissolve the high-viscosity liquid carrier material, not the active substance. The substance to be delivered can be a biologically active substance which is defined as an organic molecule (Col. 6, lines 50-65). Vitamins, and in particular vitamins E and C, are disclosed as types of organic molecules in a list that includes proteins, drugs, carbohydrates, genes, lipids and hormones.

Aldermann et al. discloses compositions for sustained release of an active organic compound comprising a thermoplastic, water-soluble, substantially non-aqueous gel matrix having dispersed therein an active organic material. The gel matrix is comprised of a water-soluble hydroxypropyl methylcellulose (HPMC) homogeneously dispersed in a plasticizer which comprises a major amount of the weight of the gel matrix. Ethyl lactate and butyl lactate are disclosed at column 4, lines 24-25, along with a number of other compounds, as plasticizers for the HPMC to form the gel matrix. The plasticizer is not used to dissolve the active substance, which is disclosed as dispersed in the gel matrix. Vitamins are disclosed as a suitable type of organic material for the compositions.

Tipton and Aldermann et al. relate to very different types of compositions than the vitamin food additives of Kirk and the vitamin food additives produced by the claimed methods. Thus, an artisan of ordinary skill would not think that it was appropriate to combine the teachings of the Tipton and Aldermann et al. with Kirk, especially since the ethyl lactate in Tipton and Aldermann et al. is used as a solvent or plasticizer for a very highly viscous materials that are not present in the vitamin food additives made by the claimed processes.

Ames discloses non-aqueous vitamin preparations for intramuscular injection of oil soluble vitamin A, D and E, an oil-and-water soluble polyoxyethylene material and a viscosity reducing agent. Ethyl lactate is disclosed at column 5, lines 15-18 as a preferred viscosity-reducing agent because it causes a minimum of muscle damage when injected. There is no suggestion or disclosure in Ames that ethyl lactate is suitable for use in a vitamin food additive for animals.

Bergemann et al. discloses biodegradable solvents comprised of a mixture of a lactate ester and an edible oil ester that has a flash point greater than 93°C for uses including stripping paint and grease removal. Ethyl lactate is disclosed as a type of lactate ester suitable for use in the biodegradable solvents. The teachings of Bergemann et al. are directed to a completely different and unrelated field of use for alkyl lactate. There is no question that this patent would not be considered (i.e., by a person of skill in this art) as being part of the teachings of the pertinent or relevant art to the invention of the present application or the inventions described in Kirk and Winstrom et al. As such, it is not proper to combine the teachings of this patent with the teachings of Kirk or any of the other cited references.

In summary, there is no disclosure or suggestion in any of the cited references that alkyl lactate would be suitable for inclusion in a vitamin food additive for animals made by the claimed methods. Kirk, Parfitt and Wickstrom et al. do not disclose or suggest vitamin food additives for animals that contain alkyl lactate. Tipton, Aldermann et al., Ames and Bergemann et al. each disclose ethyl lactate, but the compositions disclosed in each patent are so different from the vitamin food additives made by the claimed methods, as discussed above, that persons skilled in the art would not think it appropriate to combine the teachings of the references with Kirk. Moreover, none of these references discloses or suggests that alkyl lactate is suitable for use in a vitamin food additive for animals.

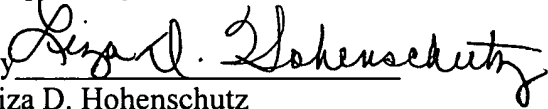
In the vitamin food additives made by the claimed methods, the alkyl lactates act as solvents to lower the viscosity of the vitamin oils to a level that allows practical handling while, at the same time, keeping the flashpoint of the additive composition at about 200°F or greater. This use of C1 to C3 alkyl lactates or C4 to C6 alkyl lactates is not disclosed or suggested in the cited prior art. Accordingly, the methods of claims 140-163 are not obvious over Kirk in view

of each of Parfitt, Winstrom et al., Tipton, Ames and Alderman et al. and Bergemann et al..  
Withdrawal of this section 103 rejection is respectfully requested.

In view of the above, the present application is believed to be in a condition ready for allowance. Reconsideration of the application is respectfully requested and an early Notice of Allowance is earnestly solicited.

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Respectfully submitted,

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